

Notice of Allowability

Application No.

10/782,702

Examiner

Alvin J. Stewart

Applicant(s)

GABBAY, SHLOMO

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to interview made 03/04/07.
2. ☒ The allowed claim(s) is/are 2, 3, 9-12, 14-19 (renumbered as 1-12).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>Attached in this communication.</u> |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gary J. Pitzer on March 14, 2007.

The application has been amended as follows:


See attachment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


ALVIN J. STEWART
PRIMARY EXAMINER
Art Unit 3738

March 15, 2007.

Attachment.

MAR-15-2007 16:07 FROM 2166214072

TO 15712734760

P.03

Serial No. 10/782,702

Docket No. SHE-6933

LISTING OF THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Cancelled)

2. (Previously Presented) The prosthesis of claim 9, wherein the strip comprises at least one of a natural material and a synthetic material.

3. (Previously Presented) The prosthesis of claim 9, wherein the strip comprises a biological tissue material.

4-8 (Cancelled)

9. (Currently Amended) A heart valve prosthesis comprising:

a valve member having an inflow end, an outflow end, and a generally cylindrical sidewall portion extending between the inflow end and the outflow end, the valve member including at least one leaflet moveable relative to the sidewall portion to provide for substantially unidirectional flow of fluid through the valve member;

a support of a substantially flexible material positioned around the sidewall portion, wherein the support is positioned around the sidewall portion of the valve member intermediate the inflow end and the outflow end of the valve member, such that an inflow end of the support is spaced apart from the inflow end of the valve member and an outflow end of the support is spaced apart from the outflow end of the valve member;

a strip of pliant material around valve member intermediate the inflow end and the outflow end of the valve member in a generally overlying relationship with the support;

a covering over a radially outer exposed surface of at least the strip; and

wherein the outflow end of the sidewall portion of the valve member includes alternating peaks and sinuses, the outflow end of the support includes alternating peaks and sinuses being configured to follow the contour of the sinuses of the valve member.

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10. (Previously Presented) The prosthesis of claim 9, further comprising an outflow extension operatively associated with and extending axially beyond and lateral each of a plurality of commissures proximal an outflow end of the valve member.

11. (Previously Presented) A heart valve prosthesis comprising:

a valve member having an inflow end, an outflow end, and a generally cylindrical sidewall portion extending between the inflow end and the outflow end, the valve member including at least one leaflet moveable relative to the sidewall portion to provide for substantially unidirectional flow of fluid through the valve member;

a support of a substantially flexible material positioned around the sidewall portion, wherein the support is positioned around the sidewall portion of the valve member intermediate the inflow end and the outflow end of the valve member, such that an inflow end of the support is spaced apart from the inflow end of the valve member and an outflow end of the support is spaced apart from the outflow end of the valve member;

a strip of pliant material around valve member intermediate the inflow end and the outflow end of the valve member in a generally overlying relationship with the support;

a covering over a radially outer exposed surface of at least the strip;

an outflow extension operatively associated with and extending axially beyond and lateral each of a plurality of commissures proximal an outflow end of the valve member; and

a sheath of a flexible material that covers the support and at least a substantial portion of an exterior part of the sidewall of the valve member, the outflow extensions being formed as outflow extending portions of the sheath that extend a predetermined distance beyond each of the plurality of commissures proximal the outflow end of the valve member.

12. (Previously Presented) The prosthesis of claim 9, wherein the valve member further comprises one of a homograft and a xenograft that includes at least two leaflets extending from a valve wall portion corresponding to the sidewall portion.

13. (Cancelled)

14. (Previously Presented) The prosthesis of claim 17, further comprising an outflow extension operatively associated with and extending axially beyond and lateral each of a plurality

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of commissures of the heart valve proximal an outflow end of the sidewall portion of the heart valve.

15. (Previously Presented) The prosthesis of claim 14, further comprising a sheath of a flexible material that covers the support and at least a substantial portion of an exterior part of the sidewall of the heart valve, the outflow extensions being formed as outflow extending portions of the sheath that extend a predetermined distance beyond each of the plurality of commissures of the heart valve proximal the outflow end of the sidewall portion of the heart valve.

16. (Previously Presented) The prosthesis of claim 17, wherein the support comprises a flexible material having a radial thickness of less than about 0.5 mm.

17. (Currently Amended) A heart valve prosthesis comprising:
a heart valve comprising:
a generally cylindrical sidewall portion extending between an inflow end and an outflow end; and

at least one leaflet located within the sidewall portion, the at least one leaflet being moveable relative to the sidewall portion to provide for substantially unidirectional flow of blood through the heart valve;

a support apparatus around the sidewall portion and positioned axially between the inflow end and the outflow end of the sidewall portion, wherein an outflow end of the support is sinusoidal with peaks extending from a generally annular base portion corresponding to a contour of the outflow end of the sidewall portion of the heart valve, such that the peaks of the support are substantially aligned with corresponding commissures of the heart valve;

a strip of pliant material around the sidewall portion of the heart valve intermediate the inflow end and the outflow end of the sidewall portion and extending radially outwardly beyond a radially outer surface of the support;

a pliable covering over the strip and attached relative to the heart valve to inhibit axial movement of the strip relative to the heart valve; and

a sheath of a flexible material interposed between the support and the strip, the sheath covering the support and at least a substantial part of the sidewall portion of the heart valve, the

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sheath having an inflow extending portion folded axially over a portion of the sheath that covers the support to define a fold seam adjacent the inflow end of the sidewall portion of the heart, a length of the sheath extending from the fold seam over the strip such that an end thereof terminates at a location adjacent an outflow end of the support

18. (Original) The prosthesis of claim 17, wherein the sheath is secured relative to the heart valve to inhibit axial movement of the strip relative to the heart valve.

19. (Original) The prosthesis of claim 17, wherein the sheath comprises a biological tissue material.

20-22. (Cancelled)